IN THE UNITED STATES DISTRICT COURT FOR THE SOUTHERN DISTRICT OF WEST VIRGINIA CHARLESTON DIVISION

IN RE: ETHICON, INC. PELVIC REPAIR SYSTEM PRODUCTS LIABILITY LITIGATION

Master File No. 2:12-MD-02327 MDL No. 2327

THIS DOCUMENT RELATES TO ALL CASES

JOSEPH R. GOODWIN U.S. DISTRICT JUDGE

DEFENDANTS' OBJECTIONS, RESPONSES AND REQUEST FOR MEET-AND-CONFER REGARDING PLAINTIFFS' "NOTICE TO TAKE ORAL DEPOSITION OF ETHICON THROUGH DESIGNATED WITNESSES" AND ACCOMPANYING REQUEST FOR PRODUCTION OF DOCUMENTS

Defendants, Ethicon Inc. ("Ethicon") and Johnson & Johnson (collectively, "Defendants") hereby respond and object to Plaintiffs' "Notice of Oral and Videotaped Deposition of Ethicon through Designated Witnesses" (the "Notice") and Exhibits "A" and "B" to the same. The Notice was filed and served on June 25, 2015 [Document 1609].

Defendants object to the Notice's Deposition Subject Matters (including but not limited to the Definitions incorporated by reference therein) to the extent that they seek testimony regarding information and/or documents that contain personal or private information about individuals other than Plaintiffs. In addition, Defendants object to the Deposition Subject Matters on the grounds that they (a) are vague and ambiguous, (b) are overly broad, (c) seek testimony that is neither relevant to the subject matter of this action nor reasonably calculated to lead to the discovery of admissible evidence, (d) are unduly burdensome and oppressive, and (e) are duplicative of extensive discovery, including depositions, already taken. Defendants further object to the Deposition Subject Matters on the grounds that the majority of subject matters,

including but not limited to subject matters that primarily seek the identification of specific documents and/or the contents thereof, are more appropriately the subject of written discovery. Defendants additionally object to the Definitions set forth in the Notice on the grounds that such Definitions are improper in the context of a deposition notice seeking oral testimony and, if taken literally, would create burdens on any witness that are not contemplated by Fed. R. Civ. P. 30(b)(6). Defendants further object to the Definitions to the extent that they purport to require Defendants to produce returned products or product exemplars.

The responses and objections contained herein are made without in any way waiving or intending to waive - but on the contrary reserving and intending to reserve - the right at any time to revise, supplement, correct or add to these objections and responses. Defendants note that no documents have been withheld from production on the basis of the objections set forth in this Response unless expressly stated. Defendants agree to meet-and-confer with Plaintiffs regarding the Notice.

Defendants' responses are based upon a reasonable investigation and diligent search of all documents that have been collected to date. These responses reflect only the current state of Defendants' understanding and belief regarding the matters upon which inquiry has been made. Discovery and investigation of the allegations asserted in the Complaint and the affirmative defenses are ongoing. As discovery in this action proceeds, it is anticipated that Defendants may discover further facts. Defendants reserve all rights to rely upon subsequently identified documents and information not included in these responses.

OBJECTIONS AND RESPONSES TO DOCUMENT REQUESTS

REQUEST NO. 1: All documents relied upon by the deponent in preparing for this deposition.

RESPONSE: Defendants object that this Request seeks information protected by the attorney work product doctrine. *See, e.g., Hickman v. Taylor*, 329 U.S. 495, 511 (1947); *In re Allen*, 106 F.3d 582, 608 (4th Cir. 1997) (observing that "choice and arrangement [of documents in witness's personnel file by counsel for witness] constitutes opinion work product because [counsel's] selection and compilation of these particular documents reveals her thought processes and theories regarding this litigation"); *Rhodes v. E.I du Pont de Nemours & Co.*, 558 F. Supp. 2d 660, 671 (S.D. W. Va. 2008) (Goodwin, C.J.) ("Courts acknowledge that the document selection process represents the mental impressions of the party's counsel and is protected work product." (internal quotation marks and alterations omitted)).

REQUEST NO. 2: All complaints and reports received by Defendants during the Relevant Time Period for TVT reporting particles or foreign material in the product or packaging.

RESPONSE: Defendants object to this Request on the grounds that it seeks personal and medical information protected by the Health Insurance Portability and Accountability Act of 1996 (HIPAA), Pub. L. No. 104-191, 110 Stat. 1936, 21 C.F.R. § 20.63, other federal and state privacy laws, and the medical privilege laws of applicable states. Defendants further object to this Request as it is overbroad and unduly burdensome. Defendants further object to this Request on the grounds that the phrase "particles or foreign material" is vague, ambiguous and undefined. Subject to and without waiving any objections, and without conceding any characterizations contained in this Request, Defendants refer to the Chats Remetrex database and the Siebel database produced at Prod. 32, Prod. 35, Prod. 36, Prod. 43, Prod.70, Prod. 90, Prod. 95, Prod. 97, Prod. 146, Prod. 187, Prod. 209, Prod. 211, Prod. 213, Prod. 219, Prod. 222, Prod. 228, Prod. 251, Prod. 267, Prod. 268, Prod. 271, Prod. 275 and Prod. 282. To the extent that Plaintiffs seek other documents, Defendants refer Plaintiffs to the MDL document production, which is in a searchable format and, as such and consistent with the

Federal Rules of Civil Procedure, Plaintiffs can locate the particular electronic documents responsive to this Request.

REQUEST NO. 3: All correspondence sent by Defendants to healthcare providers or received by Defendants from healthcare providers during the Relevant Time Period regarding reports of particles or foreign material in TVT packaging or product, including any correspondence indicating whether or not TVT products are safe to use despite particles or foreign material being present in the product or packaging.

Defendants object to this Request on the grounds that it seeks **RESPONSE:** personal and medical information protected by the Health Insurance Portability and Accountability Act of 1996 (HIPAA), Pub. L. No. 104-191, 110 Stat. 1936, 21 C.F.R. § 20.63, other federal and state privacy laws, and the medical privilege laws of applicable states. Defendants further object to this Request as it is overbroad and unduly burdensome. Defendants further object to this Request on the grounds that the phrase "particles or foreign material" is vague, ambiguous and undefined. Subject to and without waiving any objections, and without conceding any characterizations contained in this Request, Defendants refer to the Chats Remetrex database and the Siebel database produced at Prod. 32, Prod. 35, Prod. 36, Prod. 43, Prod. 70, Prod. 90, Prod. 95, Prod. 97, Prod. 146, Prod. 187, Prod. 209, Prod. 211, Prod. 213, Prod. 219, Prod. 222, Prod. 228, Prod. 251, Prod. 267, Prod. 268, Prod. 271, Prod. 275 and Prod. 282. To the extent that Plaintiffs seek other documents, Defendants refer Plaintiffs to the MDL document production, which is in a searchable format and, as such and consistent with the Federal Rules of Civil Procedure, Plaintiffs can locate the particular electronic documents responsive to this Request.

REQUEST NO. 4: All communications by Defendants discussing the cost involved with any potential recall action of any TVT lot number(s), including any discussions regarding lost sales or lost goodwill as a result of any potential action to recall or reclaim any TVT products.

RESPONSE: Defendants object to this Request as it is overbroad, unduly burdensome, vague, ambiguous, and unrestricted in time or scope. Without waiving any objections, and without conceding any characterizations contained in this Request, Defendants have a reasonable and good faith belief that the MDL document production would include at least some documents that relate in a reasonably direct manner to the subject matter of this Request. Accordingly, Defendants refer Plaintiffs to the MDL document production, which is in a searchable format and, as such and consistent with the Federal Rules of Civil Procedure, Plaintiffs can locate the particular electronic documents responsive to this Request. To the extent that additional documents, if any, are identified during the process of preparing for scheduled depositions, Defendants will make a good faith effort to produce such responsive, non-privileged documents in advance of the deposition.

REQUEST NO. 5: Any documents reflecting analyses performed by Defendants to determine the cost involved with any potential recall action of any TVT lot number(s), including any analyses performed by Defendants discussing lost sales or lost goodwill as a result of any potential action to recall or reclaim any TVT products.

RESPONSE: Defendants object to this Request as it is overbroad, unduly burdensome, vague, ambiguous, and unrestricted in time and scope. Without waiving any objections, and without conceding any characterizations contained in this Request, Defendants have a reasonable and good faith belief that the MDL document production would include at least some documents that relate in a reasonably direct manner to the subject matter of this Request. Accordingly, Defendants refer Plaintiffs to the MDL document production, which is in a searchable format and, as such and consistent with the Federal Rules of Civil Procedure, Plaintiffs can locate the particular electronic documents responsive to this Request. To the extent that additional documents, if any, are identified during the process of preparing for

scheduled depositions, Defendants will make a good faith effort to produce such responsive, non-privileged documents in advance of the deposition.

REQUEST NO. 6: Any scientific or medical analyses performed by Defendants on potential patient consequences of particles or foreign matter in TVT products or packaging.

RESPONSE: Defendants object to this Request as it is overbroad, unduly burdensome, and unrestricted in time and scope. Defendants further object to this Request on the grounds that the phrase "particles or foreign matter" is vague, ambiguous and undefined. Without waiving any objections, and without conceding any characterizations contained in this Request, Defendants have a reasonable and good faith belief that the MDL document production would include at least some documents that relate in a reasonably direct manner to the subject matter of this Request. Accordingly, Defendants refer Plaintiffs to the MDL document production, which is in a searchable format and, as such and consistent with the Federal Rules of Civil Procedure, Plaintiffs can locate the particular electronic documents responsive to this Request. To the extent that additional documents, if any, are identified during the process of preparing for scheduled depositions, Defendants will make a good faith effort to produce such responsive, non-privileged documents in advance of the deposition.

REQUEST NO. 7: All communications regarding any scientific or medical analyses performed by Defendants on potential patient consequences of particles or foreign matter in TVT products or packaging.

RESPONSE: Defendants object to this Request as it is overbroad, unduly burdensome, and unrestricted in time and scope. Defendants further object to this Request on the grounds that the phrase "particles or foreign matter" is vague, ambiguous and undefined. Without waiving any objections, and without conceding any characterizations contained in this Request, Defendants have a reasonable and good faith belief that the MDL document production would include at least some documents that relate in a reasonably direct manner to the subject

matter of this Request. Accordingly, Defendants refer Plaintiffs to the MDL document production, which is in a searchable format and, as such and consistent with the Federal Rules of Civil Procedure, Plaintiffs can locate the particular electronic documents responsive to this Request. To the extent that additional documents, if any, are identified during the process of preparing for scheduled depositions, Defendants will make a good faith effort to produce such responsive, non-privileged documents in advance of the deposition.

REQUEST NO. 8: All communications between Defendants' employees regarding the 10 returned TVT-O products described in exhibit A-4.

RESPONSE: Without waiving any objections, and without conceding any characterizations contained in this Request, Defendants have a reasonable and good faith belief that the MDL document production would include at least some documents that relate in a reasonably direct manner to the subject matter of this Request. Accordingly, Defendants refer Plaintiffs to the MDL document production, which is in a searchable format and, as such and consistent with the Federal Rules of Civil Procedure, Plaintiffs can locate the particular electronic documents responsive to this Request. *See, e.g.,* ETH.MESH.13226457, ETH.MESH.12943537 and ETH.MESH.12943536. To the extent that additional documents, if any, are identified during the process of preparing for scheduled depositions, Defendants will make a good faith effort to produce such responsive, non-privileged documents in advance of the deposition.

REQUEST NO. 9: All communications between Defendants and third parties regarding the 10 returned TVT-O products described in exhibit A-4.

RESPONSE: Without waiving any objections, and without conceding any characterizations contained in this Request, Defendants have a reasonable and good faith belief that the MDL document production would include at least some documents that relate in a

reasonably direct manner to the subject matter of this Request. Accordingly, Defendants refer Plaintiffs to the MDL document production, which is in a searchable format and, as such and consistent with the Federal Rules of Civil Procedure, Plaintiffs can locate the particular electronic documents responsive to this Request. To the extent that additional documents, if any, are identified during the process of preparing for scheduled depositions, Defendants will make a good faith effort to produce such responsive, non-privileged documents in advance of the deposition.

REQUEST NO. 10: Any documents reflecting analyses or testing by Defendants on the 10 returned TVT-O products described in exhibit A-4.

RESPONSE: Without waiving any objections, and without conceding any characterizations contained in this Request, Defendants have a reasonable and good faith belief that the MDL document production would include at least some documents that relate in a reasonably direct manner to the subject matter of this Request. Accordingly, Defendants refer Plaintiffs to the MDL document production, which is in a searchable format and, as such and consistent with the Federal Rules of Civil Procedure, Plaintiffs can locate the particular electronic documents responsive to this Request. To the extent that additional documents, if any, are identified during the process of preparing for scheduled depositions, Defendants will make a good faith effort to produce such responsive, non-privileged documents in advance of the deposition.

REQUEST NO. 11: Any operating procedures, standards, worksheets, or specifications used by Defendants during the Relevant Time Period for acceptance or rejection of TVT product based on particles or foreign material in the product or packaging, including but not limited to: TM403-166, EMQD10, VSE0007, C/L-E0038, and TAPPI 213/T437 including all historical versions of such procedures and standards and dates of use for each procedure, standard, or specification.

RESPONSE: Defendants object to this Request as it is overbroad, unduly burdensome and unrestricted in scope. Defendants further object to this Request on the grounds that the phrase "particles or foreign material" is vague, ambiguous and undefined. Without waiving any objections, and without conceding any characterizations contained in this Request, Defendants have a reasonable and good faith belief that the MDL document production would include at least some documents that relate in a reasonably direct manner to the subject matter of this Request. Accordingly, Defendants refer Plaintiffs to the MDL document production, which is in a searchable format and, as such and consistent with the Federal Rules of Civil Procedure, Plaintiffs can locate the particular electronic documents responsive to this Request. See, e.g., ETH.MESH.11495552 ETH.MESH.11495560, ETH.MESH.12182368 ETH.MESH.12182370, ETH.MESH.04465749 - ETH.MESH.04465750, ETH.MESH.22258524 ETH.MESH.22258534, ETH.MESH.02281622 ETH.MESH.02281632, ETH.MESH.04465756 ETH.MESH.04465766, ETH.MESH.04465802 ETH.MESH.04465813, ETH.MESH.04465872 - ETH.MESH.04465883, ETH.MESH.04465891 ETH.MESH.04465902, ETH.MESH.04465918 ETH.MESH.04465929, ETH.MESH.04465935 ETH.MESH.04465947, ETH.MESH.04465954 ETH.MESH.04465966, ETH.MESH.22258535 - ETH.MESH.22258547, ETH.MESH.15133342 ETH.MESH.15133354, ETH.MESH.16210533 ETH.MESH.16210545, ETH.MESH.22258560, ETH.MESH.22258575 ETH.MESH.22258548 ETH.MESH.22258588, ETH.MESH.22258561 - ETH.MESH.22258574, ETH.MESH.04460011 - ETH.MESH.04460014, and ETH.MESH.01310202. To the extent that additional documents, if any, are identified during the process of preparing for scheduled depositions, Defendants will

make a good faith effort to produce such responsive, non-privileged documents in advance of the deposition.

REQUEST NO. 12: All communications between Defendants' employees during the Relevant Time Period regarding changes to operating procedures, standards, worksheets, or specifications used by Defendants for acceptance or rejection of TVT product based on particles or foreign material in the product or packaging including but not limited to: TM403-166, EMQD10, VSE0007, C/L-E0038, and TAPPI 213/T437.

RESPONSE: Defendants object to this Request as it is overbroad, unduly burdensome and unrestricted in scope. Defendants further object to this Request on the grounds that the phrase "particles or foreign material" is vague, ambiguous and undefined. Without waiving any objections, and without conceding any characterizations contained in this Request, Defendants have a reasonable and good faith belief that the MDL document production would include at least some documents that relate in a reasonably direct manner to the subject matter of this Request. Accordingly, Defendants refer Plaintiffs to the MDL document production, which is in a searchable format and, as such and consistent with the Federal Rules of Civil Procedure, Plaintiffs can locate the particular electronic documents responsive to this Request. To the extent that additional documents, if any, are identified during the process of preparing for scheduled depositions, Defendants will make a good faith effort to produce such responsive, non-privileged documents in advance of the deposition.

REQUEST NO. 13: All documents maintained by defendants reflecting inspections, acceptance, and rejections of TVT products based on Defendants' specifications and operating procedures during the Relevant Time Period.

RESPONSE: Defendants object to this Request as it is overbroad, unduly burdensome and unrestricted in scope. Without waiving any objections, and without conceding any characterizations contained in this Request, Defendants have a reasonable and good faith belief that the MDL document production would include at least some documents that relate in a

reasonably direct manner to the subject matter of this Request. Accordingly, Defendants refer Plaintiffs to the MDL document production, which is in a searchable format and, as such and consistent with the Federal Rules of Civil Procedure, Plaintiffs can locate the particular electronic documents responsive to this Request. *See*, *e.g.*, ETH.MESH.13226457, ETH.MESH.12943537 and ETH.MESH.12943536. To the extent that additional documents, if any, are identified during the process of preparing for scheduled depositions, Defendants will make a good faith effort to produce such responsive, non-privileged documents in advance of the deposition.

REQUEST NO. 14: All documents reflecting investigation, analyses, conclusions, and corrective and preventative actions regarding particles or foreign material in products or packaging of TVT products during the Relevant Time Period.

RESPONSE: Defendants object to this Request as it is overbroad and unduly burdensome. Defendants further object to this Request on the grounds that the phrase "particles or foreign material" is vague, ambiguous and undefined. Without waiving any objections, and without conceding any characterizations contained in this Request, Defendants have a reasonable and good faith belief that the MDL document production would include at least some documents that relate in a reasonably direct manner to the subject matter of this Request. Accordingly, Defendants refer Plaintiffs to the MDL document production, which is in a searchable format and, as such and consistent with the Federal Rules of Civil Procedure, Plaintiffs can locate the particular electronic documents responsive to this Request. *See, e.g.,* ETH.MESH.13226457, ETH.MESH.12943537 and ETH.MESH.12943536. To the extent that additional documents, if any, are identified during the process of preparing for scheduled depositions, Defendants will make a good faith effort to produce such responsive, non-privileged documents in advance of the deposition.

REQUEST NO. 15: All communications regarding investigation, analyses, conclusions, and corrective and preventative actions regarding particles or foreign material in products or packaging of TVT products during the Relevant Time Period.

RESPONSE: Defendants object to this Request as it is overbroad and unduly burdensome. Defendants further object to this Request on the grounds that the phrase "particles or foreign material" is vague, ambiguous and undefined. Without waiving any objections, and without conceding any characterizations contained in this Request, Defendants have a reasonable and good faith belief that the MDL document production would include at least some documents that relate in a reasonably direct manner to the subject matter of this Request. Accordingly, Defendants refer Plaintiffs to the MDL document production, which is in a searchable format and, as such and consistent with the Federal Rules of Civil Procedure, Plaintiffs can locate the particular electronic documents responsive to this Request. To the extent that additional documents, if any, are identified during the process of preparing for scheduled depositions, Defendants will make a good faith effort to produce such responsive, non-privileged documents in advance of the deposition.

REQUEST NO. 16: All documentation regarding returned TVT complaint samples, including but not limited to: testing and analyses of returned samples, and documents reflecting receipt, storage, or disposal of said samples.

RESPONSE: Defendants object to this Request as it is overbroad, unduly burdensome, and unrestricted in time and scope. Without waiving any objections, and without conceding any characterizations contained in this Request, Defendants have a reasonable and good faith belief that the MDL document production would include at least some documents that relate in a reasonably direct manner to the subject matter of this Request. Accordingly, Defendants refer Plaintiffs to the MDL document production, which is in a searchable format and, as such and consistent with the Federal Rules of Civil Procedure, Plaintiffs can locate the

particular electronic documents responsive to this Request. *See, e.g.*, ETH.MESH.13207079 – ETH.MESH.13207083. To the extent that additional documents, if any, are identified during the process of preparing for scheduled depositions, Defendants will make a good faith effort to produce such responsive, non-privileged documents in advance of the deposition.

REQUEST NO. 17: All documents maintained by defendants reflecting inspections, maintenance, and cleaning of equipment used by Defendants for cutting TVT mesh, packaging TVT, or sterilization of TVT during the Relevant Time Period.

RESPONSE: Defendants object to this Request as it is overbroad, unduly burdensome and unrestricted in scope. Without waiving any objections, and without conceding any characterizations contained in this Request, Defendants have a reasonable and good faith belief that the MDL document production would include at least some documents that relate in a reasonably direct manner to the subject matter of this Request. Accordingly, Defendants refer Plaintiffs to the MDL document production, which is in a searchable format and, as such and consistent with the Federal Rules of Civil Procedure, Plaintiffs can locate the particular electronic documents responsive to this Request. To the extent that additional documents, if any, are identified during the process of preparing for scheduled depositions, Defendants will make a good faith effort to produce such responsive, non-privileged documents in advance of the deposition.

REQUEST NO. 18: All documents maintained by defendants reflecting cleaning and inspection of manufacturing areas used by Defendants for cutting TVT mesh, packaging TVT, or sterilization of TVT during the Relevant Time Period.

RESPONSE: Defendants object to this Request as it is overbroad, unduly burdensome and unrestricted in scope. Without waiving any objections, and without conceding any characterizations contained in this Request, Defendants have a reasonable and good faith belief that the MDL document production would include at least some documents that relate in a

reasonably direct manner to the subject matter of this Request. Accordingly, Defendants refer Plaintiffs to the MDL document production, which is in a searchable format and, as such and consistent with the Federal Rules of Civil Procedure, Plaintiffs can locate the particular electronic documents responsive to this Request. To the extent that additional documents, if any, are identified during the process of preparing for scheduled depositions, Defendants will make a good faith effort to produce such responsive, non-privileged documents in advance of the deposition.

Respectfully submitted,

ETHICON, INC. AND JOHNSON & JOHNSON

/s/ Christy D. Jones

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UNITED STATES DISTRICT COURT SOUTHERN DISTRICT OF WEST VIRGINIA AT CHARLESTON

IN RE: ETHICON, INC. PELVIC REPAIR SYSTEM PRODUCTS LIABILITY LITIGATION

Master File No. 2:12-MD-02327 MDL No. 2327

THIS DOCUMENT RELATES TO ALL CASES

JOSEPH R. GOODWIN U.S. DISTRICT JUDGE

CERTIFICATE OF SERVICE

I, Christy D. Jones, certify that on July 6, 2015, I electronically filed the foregoing document with the Clerk of the Court using the CM/ECF system which will send notification of such filing to the CM/ECF participants registered to receive service in this MDL.

/s/ Christy D. Jones

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